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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,350	Applicant(s) IGNATIUS, FRANCIS X.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2005.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-32, 49-62 is/are pending in the application.
 4a) Of the above claim(s) 23, 24, 26, 27, 30-32 and 49-62 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 17-22, 25, 28 and 29 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Amendment filed 11/19/2005 is acknowledged. Claims 49-62 are added. Claims 17-32,49-62 are pending. Claims 23,24,26,27,30-32 remain withdrawn from consideration.

New claims 60-62 are directed to non-elected subject matter, similarly to the withdrawn claims 30-32, and are thus also withdrawn from consideration as drawn to non-elected group.

New claims 49-59 are directed to non-elected species of polyester – anionic polylactide-co-glycolide containing COOH groups was elected as a charged polyester – and are withdrawn from consideration as drawn to non-elected species.

Claims 17-22,25,28,29 are being examined to the extent they read on the elected species: somatostatin analogue as a peptide, polylactide-co-glycolide containing COOH groups as a charged polyester, dichloromethane as an organic solvent, and sodium oleate as surfactant.

Applicant's arguments have been fully considered and they are deemed to be persuasive. Rejections of record are withdrawn. The following new rejection was deemed necessary.

Claim Rejections - 35 USC § 103

Claims 17-22,25,28,29 rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchinson et al (US patent 5,889,110) in view of Okada et al (US 5,631,020) or Stap et al (US 4542789) and further in view of Shalaby et al (US 5672659)

The instant claims are drawn to method of preparing peptide-containing microcapsules comprising

- dissolving a salt of a peptide complexed with a charged polyester in an organic solvent to form a solution;
- dispersing the above solution in an aqueous solution containing surfactant;
- evaporating the organic solvent.

The elected species are: somatostatin analogue as a peptide, polylactide-co-glycolide containing COOH groups as a charged polyester, dichloromethane as an organic solvent, and sodium oleate as surfactant.

Hutchinson et al teach preparing salts of peptides and charged polyesters and their further use in preparing peptide sustained release microcapsule formulations. In particular, the reference teaches that peptide-polyester salt is dissolved in organic solvent, such as dichloromethane, dispersed in aqueous solution, with subsequent evaporation of the organic solvent. See col. 13, lines 48-60, and col. 28, Example 6. The resulting microparticles have the shape of microspheres (col. 15, lines 22-25). A preferable polyester is polylactide-co-glycolide (col. 3, lines 56,57; Example 6); suitable

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peptide can be somatostatin (col. 2, line 17), preferable organic solvent is dichloromethane (e.g., Example 6). The aqueous solution might contain polyvinyl alcohol as a viscosity-enhancing polymer

The reference teaches all limitations of the claimed method, except for the use of a surfactant in the resulting aqueous solution. However, use of surfactants for stabilizing protein pharmaceutical formulations in general, and for stabilizing oil-in-water protein pharmaceutical formulations in particular is well known. See, for example, Okada et al (US 5,631,020) demonstrating use of sodium oleate as surfactant to stabilize formulation of protein microcapsules. Therefore, it would have been prima facie obvious at the time the invention was made to be motivated to use a surfactant, such as sodium oleate, to stabilize the formulation obtained per method of Hutchinson et al, and thus to arrive at the instant invention.

Alternatively, as Hutchinson reference suggest using viscosity enhancing agents in the resulting aqueous solution, and suggests use of polyvinyl alcohol, in particular, it would be obvious to a skilled artisan that any other agent suitable for maintaining viscosity in a pharmaceutical formulation would be expected to be functionally equivalent. Sodium oleate is known as a viscosity enhancing agent. See Stap et al (US 4542789), claim 3, for example.

Further, with respect to somatostatin as a peptide, although Hutchinson et al mention this peptide in the general list of peptides suitable for preparing microspheres, the reference does not address the peptide as the preferred embodiment. Note, however, that the reference of Shalaby et al (US 5672659), which teaches preparing

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salts of peptides and charged polyesters used in the instant invention, addresses somatostatin as a preferred peptide for preparing such salts. See claim 31, for example.

With respect to claims 20,21, selection of an appropriate amount of salt (it is understood that the amounts of polyester addressed in the claim refer to the amounts of peptide-polyester salt) to produce a solution as intended, would be obvious to one skilled in the art as a result of a routine optimization.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb
11/23/2005